

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF GEORGIA**

CONCORDIA PHARMACEUTICALS
INC., S.A.R.L., CONCORDIA
PHARMACEUTICALS (US) INC.,
and ADVANZ PHARMA CORP.,
Plaintiffs,

v.

WINDER LABORATORIES, LLC,
and STEVEN PRESSMAN,
Defendants.

WINDER LABORATORIES, LLC,
and STEVEN PRESSMAN,
Counterclaim Plaintiffs,

v.

CONCORDIA PHARMACEUTICALS
INC., S.A.R.L., CONCORDIA
PHARMACEUTICALS (US) INC.,
and ADVANZ PHARMA CORP.,
Counterclaim Defendants.

Civil Action No. 2:16-cv-00004-RWS

JURY TRIAL DEMANDED

ATTACHMENT D

COUNTERCLAIM DEFENDANTS'

OUTLINE OF THE CASE

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EXHIBIT D, COUNTERCLAIM DEFENDANTS' OUTLINE OF THE CASE

I. Succinct Factual Summary of General, Special and Affirmative Defenses

1. The Claims

On April 15, 2020, Winder filed its Amended Answer and Counterclaims (Dkt. No. 305), asserting claims for false advertising under the Lanham Act (Count I), tortious interference with Contractual Relationships (Count II), tortious

interference with business relationships (Count III), violation of Georgia's Uniform Deceptive Trade Practice Act ("GUDTPA") (Count IV), and common law unfair competition (Count V).

Winder's claims are based on the same central allegation that Concordia engaged in false advertising by having letters sent to third parties ("Concordia's letters"), which contained two categories of allegedly false statements, (1) Winder's products are unlawful products, and (2) Winder's products are potentially unsafe.

At trial, Concordia intends to present a defense that Winder cannot meet its burden of proof with regard to the claims involving Concordia's letters because they do not constitute commercial advertisement or promotion, are not literally false, are not misleading, were not intended to mislead consumers, caused no deception, and caused no injury. Concordia will establish the letters statements are nonactionable opinion, true at the time they were made, and/or were supported by FDA guidance.

2. Winder's Requested Remedies

Concordia intends to present a uniform defense at trial that Winder is not entitled to any form of relief because it cannot establish liability with respect to any underlying claim asserted against Concordia. To the extent that liability is

found on one or more of these claims, however, Concordia intends to present the following defenses to each specific form of remedy requested by Winder.

i. Damages

Concordia intends to present a defense at trial that Winder is not entitled to actual damages because it cannot meet its burden of proving the quantum of those damages, nor can it prove a causal connection between any false advertising and damages. Winder is not entitled to any other relief.

3. Affirmative Defenses

i. First Amendment

Concordia intends to present an affirmative defense at trial that Winder's claims are barred from injunctive relief and monetary damages by the free speech clause of the First Amendment to the United States Constitution.

ii. Preclusion and Preemption

Concordia intends to present an affirmative defense at trial that Winder's claims are barred from injunctive relief and monetary damages because its claims are precluded and preempted by federal law.

iii. Unclean Hands

Concordia intends to present an affirmative defense at trial that Winder's claims are barred by its own unclean hands in disseminating willfully false

advertisements regarding its Phenohydro and B-Donna products and by claiming Concordia's Donnatal is unapproved.

iv. Failure to Mitigate Damages

Concordia intends to present an affirmative defense at trial that Winder's claims are barred by its failure to mitigate the damages it claims were caused by the Concordia's letters through its own advertisements or otherwise.

v. Superseding Cause

Concordia intends to assert an affirmative defense at trial that Winder is barred from injunctive relief and monetary damages because any injury it suffered was caused by separate and superseding causes or by its own conduct.

II. Listing of Statutes and Illustrative Case Law

1. Defenses Under the Lanham Act (Count I)

For a description of the elements that Winder must establish to prevail on its Lanham Act claim, see 15 U.S.C. § 1125 (a), *N. Am. Medical Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211 (11th Cir. 2008); *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002); *Podiatrist Ass'n, Inc. v. La Cruz Azul de Puerto Rico, Inc.*, 332 F.3d 6 (1st Cir. 2003); *Optimum Tech. Inc. v. Home Depot USA, Inc.*, No. 1:04 CV 3260 TWT, 2005 WL 3307508 (N.D. Ga. Dec. 5, 2005).

i. Commercial Advertisement or Promotion

Concordia intends to present a defense at trial that Winder cannot meet its burden of establishing that Concordia's letters represent commercial advertisement or promotion. See 15 U.S.C. § 1125 (a), *see also Suntree Tech., Inc. v. Ecosense Int'l, Inc.*, 693 F.3d 1338 (11th Cir. 2012); *Tobinick v. Novella*, 848 F.3d 935 (11th Cir. 2017); *Podiatrist Ass'n, Inc. v. La Cruz Azul de Puerto Rico, Inc.*, 332 F.3d 6 (1st Cir. 2003); *Optimum Tech. Inc. v. Home Depot USA, Inc.*, No. 1:04 CV 3260 TWT, 2005 WL 3307508 (N.D. Ga. Dec. 5, 2005); *Futuristic Fences, Inc. v. Illusion Fence Corp.*, 558 F.Supp.2d 1270 (S.D. Fla. 2008); *Avery Dennison Corp. v. Acco Brands, Inc.*, 2000 WL 986995 (C.D. Cal. Feb. 22, 2000); *Zinus Inc. v. Simmons Bedding Co.*, 2007 WL 4287391 (N.D. Cal. Dec. 6, 2007).

ii. Literally False or Misleading

Concordia intends to present a defense at trial that Winder cannot meet its burden of establishing that Concordia's letters are literally false or misleading. See *Hickson Corp. v. N. Crossarm Co., Inc.*, 357 F.3d 1256 (11th Cir. 2004); *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002); *Osmose Inc. v. Ciance LLC*, 612 F.3d 1298 (11th Cir. 2010); *FieldTurf USA, Inc. v. TenCate Thiolon Middle E., LLC*, 945 F.Supp.2d 1379 (N.D. Ga. 2013); *Schutz Container Sys., Inc. v. Mauser Corp.*, 2012 BL 84217 (N.D. Ga. Mar. 28, 2012); *Moulton v. VC3*, No. 1:00-cv-434-TWT, 2000 WL 33310901 (N.D. Ga. Nov. 7, 2000)); *Am. Council of Certified Podiatric Physicians &*

Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 185 F.3d 606 (6th Cir. 1999); *Presidio Enters., Inc. v. Warner Bros. Distrib. Corp.*, 784 F.2d 674 (5th Cir. 1986); *Gertz v. Robert Welch*, 418 U.S. 323 (1974); *General Cigar Holdings, Inc. v. Altadis, S.A.*, 205 F.Supp.2d 1335 (S.D. Fla. 2002); *Cashmere & Camel Hair Mfrs. Inst. V. Saks Fifth Ave.*, 284 F.3d 302 (1st Cir. 2002); *3M Innovative Props. Co. v. Dupont Dow Elastomers LLC*, 361 F.Supp.2d 958 (D. Minn. 2005); see also § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); 21 U.S.C. § 351(a)(2)(B).

iii. Consumer Deception

Concordia intends to present a defense at trial that Winder cannot meet its burden of proving that Concordia's letters deceived or had the capacity to deceive consumers. See *Osmose Inc. v. Ciance LLC*, 612 F.3d 1298 (11th Cir. 2010); *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329 (8th Cir. 1999); *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002); *Hickson Corp. v. Northern Crossarm Co., Inc.*, 357 F.3d 1256 (11th Cir. 2004); *Johnson & Johnson Merck Consumer Pharm. Cl. v. Smithkline Beecham Corp.*, 960 F.2d 294 (2d Cir. 1992); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990); *Kwan Software Eng'g, Inc. v. Foray Technologies, LLC*, C 12-03762 SI, 2013 WL 244999 (N.D. Cal. Jan. 22, 2013).

iv. Material Effect on Purchasing Decisions

Concordia intends to present a defense at trial that Winder cannot meet its burden of proving that Concordia's letters had a material effect on the purchasing decisions of consumers. See *Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002); *Cashmere & Camel Hair Mfrs. Inst. V. Saks Fifth Ave.*, 284 F.3d 302 (1st Cir. 2002); *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841 (2d Cir. 1997).

v. Injury

Concordia intends to present a defense at trial that Winder cannot meet its burden of proving that Concordia's letters caused Winder injury. See *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F.Supp.2d 1293 (N.D. Ga. 2008); *Snac Lite, LLC v. Nuts 'N More, LLC*, 2016 BL 381145 (N.D. Ala. Nov. 16, 2016); *Ameritox, Ltd. v. Millennium Labs., Inc.*, 2014 WL 1456347 (M.D. Fla. Apr. 14, 2014); *Innovation Ventures, LLC v. Bhelliom Enterprises Corp.*, 529 Fed.Appx. 560 (6th Cir. 2013); *Coach, Inc. v. Becka*, No. 2012 WL 5398830 (M.D.Ga. Nov. 2, 2012); *In re Viagra Prods. Liab. Litig.*, 658 F.Supp.2d 950 (D. Minn. 2009).

2. Defenses Under Tortious Interference With Contractual Relationships (Count II)

Concordia will present a defense at trial that Winder's tortious interference claim fails for the same reasons as its Lanham Act claim. Concordia also intends to present a defense at trial that Winder cannot make out its burden of proof with respect to its tortious interference claim because Winder cannot prove one or more

elements of its claim. See *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256 (11th Cir. 2004); *Moulton v. VC3*, No. 1:00-CV-434-TWT, 2000 BL 883 (N.D. Ga. Nov. 7, 2000); *Parks v. Multimedia Techs., Inc.*, 239 Ga.App. 282 (Ga.App. 1999).

3. Defenses Under Tortious Interference With Business Relationships (Count III)

Concordia will present a defense at trial that Winder's tortious interference claim fails for the same reasons as its Lanham Act claim. Concordia also intends to present a defense at trial that Winder cannot make out its burden of proof with respect to its tortious interference claim because Winder cannot prove one or more elements of its claim. See *Disaster Servs., Inc. v. ERC P'ship*, 228 Ga. App. 739 (1998); *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F. Supp.2d 1293 (N.D. Ga. 2008); *Hayes v. Irwin*, 541 F.Supp. 397 (N.D. Ga. 1982); *Am. Southern Ins. Group, Inc. v. Goldstein*, 291 Ga. App. 1 (2008); *Galardi v. Steele Inman*, 266 Ga. App. 515 (2004); *Camp v. Eichelkraut*, 246 Ga. App. 275 (2000); *Worldwide Primates, Inc. v. McGreal*, 26 F.3d 1089 (11th Cir. 1994); *B & F Sys., Inc. v. Leblanc*, 2011 WL 4103576 (M.D. Ga. Sept. 14, 2011).

4. Defenses Under GUDTPA (Count IV)

Concordia will present a defense at trial that Winder's GUDTPA claim fails for the same reasons as its Lanham Act claim. Concordia also intends to present a defense at trial that Winder cannot make out its burden of proof with respect to its GUDTPA claim because Winder cannot prove one or more elements of its claim.

Optimum Techs., Inc. V. Henkel Consumer Adhesives, Inc., 496 F.3d 1231 (11th Cir. 2007); *Graceway Pharm., LLC v. River's Edge Pharm., LLC*, 2009 U.S. Dist. LEXIS 103589 (N.D. Ga. 2009); *Energy Four, Inc. v. Dornier Medical Sys., Inc.*, 765 F.Supp. 724 (N.D. Ga. 1991); O.C.G.A. § 10-1-372(a)(8); O.C.G.A. § 10-1-372(5), (7)-(8), (12); *Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.*, 716 F.2d 833 (11th Cir. 1983); *Energy Four, Inc. v. Dornier Medical Sys., Inc.*, 765 F.Supp. 724 (N.D. Ga. 1991).

5. Defenses Under Common Law Unfair Competition (Count V)

Concordia will present a defense at trial that Winder's common law unfair competition claim fails for the same reasons as its Lanham Act claim. Concordia also intends to present a defense at trial that Winder cannot make out its burden of proof with respect to its common law unfair competition claim because Winder cannot prove one or more elements of its claim. *Optimum Techs., Inc. V. Henkel Consumer Adhesives, Inc.*, 496 F.3d 1231 (11th Cir. 2007); *Energy Four, Inc. v. Dornier Medical Sys., Inc.*, 765 F.Supp. 724 (N.D. Ga. 1991); *Graceway Pharm., LLC v. River's Edge Pharm., LLC*, 2009 U.S. Dist. LEXIS 103589 (N.D. Ga. 2009).

6. Defenses to Remedies Sought by Winder

i. Damages

Concordia intends to present a defense at trial that Winder is not entitled to damages because it cannot establish liability under any theory, and cannot meet its burden of proving a quantum of actual damages or that any such damages were proximately caused by Concordia's letters. For a description of the elements that Winder must prove in order to recover actual damages, see 15 U.S.C. § 1117(a); *Maurer Rides USA, Inc. v. Beijing Shibaolia Amusement Equip. Co.*, 2012 BL 426545 (M.D. Fla. May 30, 2012); *Keg Techs., Inc. v. Laimer*, 436 F.Supp.2d 1364 (N.D. Ga. 2006); *Babbit Elecs., Inc. v. Dynascan Corp.*, 38 F.3d 1161 (11th Cir. 1994); *In re eBay Litig.*, 2012 U.S. Dist. LEXIS 128616 (N.D. Cal. Sept. 10, 2012); *Groce v. Claudat*, 2013 U.S. Dist. LEXIS 61699 (S.D. Cal. Apr. 30, 2013); *Toni's Alpacas, Inc. v. Evans*, No. 09-CV-02045-REB-CBS, 2010 WL 3730382 (D. Colo. Sept. 16, 2010); *Caraker v. Sandoz Pharm. Corp.*, 172 F.Supp.2d 1046 (S.D. Ill. 2001); *Weinberg v. Whatcom Cnty.*, 241 F.3d 746 (9th Cir. 2001); *Ware v. Rodale Press, Inc.*, 322 F.3d 218 (3d Cir. 2003); *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F.Supp.2d 1293 (N.D. Ga. 2008); *Quick Techs., Inc. v. Sage Group PLC*, 313 F.3d 338 (5th Cir. 2002); *Balance Dynamics Corp. v. Schmit Industries, Inc.*, 204 F.3d 683 (6th Cir. 2000); *Castrol, Inc. v. Pennzoil Quaker State Co.*, 169 F.Supp.2d 332 (D.N.J. 2001); *Optimum Techs., Inc. v. Home Depot U.S.A., Inc.*, 217 Fed. Appx. 899 (11th Cir. 2007).

7. Affirmative Defenses

i. First Amendment

Concordia intends to assert an affirmative defense at trial that Winder is barred from injunctive relief and monetary damages by the free speech clause of the First Amendment to the United States Constitution, U.S. Const. amend. I, cl. 2.

ii. Preclusion and Preemption

Concordia intends to assert an affirmative defense at trial that Winder is barred from injunctive relief and monetary damages because its claims are precluded and preempted by federal law. See the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq; *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2238 (2014); *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F.Supp.3d 1323 (N.D. Ga. 2016); *JHP Pharms., LLC v. Hospira, Inc.*, 52 F.Supp.3d 992 (C.D. Cal. 2014).

iii. Unclean Hands

Concordia intends to assert an affirmative defense at trial that Winder is barred from injunctive relief and monetary damages by its own unclean hands in disseminating willfully false advertising, demonstrably false statements, misrepresentations, and misstatements of law about its products B-Donna and Phenohytro to Concordia's potential and existing customers and caused Concordia to lose both sales of its Donnatal products and customers. See 15 U.S.C.A. § 1117; *see also Burger King Corp. v. Mason*, 855 F.2d 779 (11th Cir. 1988); *Katiroll Co.*,

Inc. v. Kati Roll and Platters, Inc., No. 10-3620, 2011 WL 2294260, *2 (D.N.J. June 8, 2011) (“The defense of unclean hands is applicable to all claims brought under the Lanham Act . . . even money damages in the Lanham Act are subject to the principles of equity.”). Concordia will prevail on its unclean hands defense if it can meet the burden of establishing that Winder’s acts “have an ‘immediate and necessary relation’ to the remedy sought in the ... litigation.” *HiTech Pharmaceuticals, Inc. v. Demelo*, 1:07-CV-RWS, 2009 WL 901156, at *9 (N.D. Ga. Mar. 31, 2009); *see also Boone v. Corestaff Support Servs.*, 805 F.Supp.2d 1362, 1371-72 (N.D. Ga. 2011) (unclean hands defense “generally prevents the court from even considering the merits of plaintiff’s claims”).

iv. Failure to Mitigate Damages

Concordia intends to assert a defense at trial that Winder’s recovery, if any, should be barred or reduced by its own failure to mitigate damages. Concordia will prevail on its mitigation defense if it can meet the burden of establishing that Winder failed to exercise reasonable effort or ordinary care and diligence to avoid the damages that it seeks to recover from Concordia. *See Pattee v. Georgia Ports Auth.*, 512 F.Supp.2d 1372, 1379 (S.D. Ga. 2007) (“Under common law, however, plaintiffs are not entitled to recover all actual losses proximately caused by defendant’s actions. Specifically, ‘one injured by the tort of another is not entitled to recover damages for any harm that he could have avoided by the use of

reasonable effort or expenditure after the commission of the tort.”); *Wachovia Bank of Ga. v. Namik*, 275 Ga. App. 229, 232, 620 S.E.2d 470, 473 (2005) (“And in a Georgia tort action, parties are required to mitigate their damages; they are bound to reduce their damages ‘as far as is practicable by the use of ordinary care and diligence ... If a plaintiff fails to exercise ordinary care, his damages are limited to those he would have suffered had damages been properly mitigated.”).

v. Superseding Cause

Concordia intends to assert an affirmative defense at trial that Winder is barred from injunctive relief and monetary damages because any injury it suffered was caused by separate and superseding causes or by its own conduct.